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110TH CONGRESS
2D SESSION

H. R. 6432

To amend the Federal Food, Drug, and Cosmetic Act to revise and extend the animal drug user fee program, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

JULY 8, 2008

Mr. PALLONE (for himself, Mr. DINGELL, Mr. BARTON of Texas, Mr. DEAL of Georgia, and Mr. TOWNS) introduced the following bill; which was referred to the Committee on Energy and Commerce

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A BILL

To amend the Federal Food, Drug, and Cosmetic Act to revise and extend the animal drug user fee program, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE; REFERENCES; FINDING.

(a) SHORT TITLE.—This Act may be cited as the ''Animal Drug User Fee Amendments of 2008''.

(b) REFERENCES IN ACT.—Except as otherwise specified, amendments made by this Act to a section or other provision of law are amendments to such section or other

provision of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.).

(c) FINDING.—Congress finds that the fees authorized by the amendments made in this Act will be dedicated toward expediting the animal drug development process and the review of new and supplemental animal drug applications and investigational animal drug submissions as set forth in the goals identified, for purposes of part 4 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act, in the letters from the Secretary of Health and Human Services to the Chairman of the Committee on Energy and Commerce of the House of Representatives and the Chairman of the Committee on Health, Education, Labor, and Pensions of the Senate as set forth in the Congressional Record.

SEC. 2. DEFINITIONS.

Section 739 (21 U.S.C. 379j–11) is amended—

(1) in paragraph (6), by striking ‘‘, except for an approved application for which all subject products have been removed from listing under section 510’’ and inserting ‘‘that has not been withdrawn’’;

(2) in paragraph (10), by striking ‘‘year being 2003’’ and inserting ‘‘month being October 2002’’;

(3) by redesignating paragraph (11) as paragraph (12); and

(4) by inserting after paragraph (10) the following:

''(11) The term 'person' includes an affiliate thereof.''.

SEC. 3. AUTHORITY TO ASSESS AND USE ANIMAL DRUG FEES.

(a) TYPES OF FEES.—Section 740(a) (21 U.S.C. 379j–12(a)) is amended—

(1) in paragraph (1)(A)(i), by inserting after ''for an animal drug application'' the following: '', except an animal drug application subject to the criteria set forth in section 512(d)(4)''; and

(2) by amending paragraph (1)(A)(ii) to read as follows:

''(ii) A fee established in subsection (b), in an amount that is equal to 50 percent of the amount of the fee under clause (i), for—

''(I) a supplemental animal drug application for which safety or effectiveness data are required; and

''(II) an animal drug application subject to the criteria set forth in section 512(d)(4).''.

(b) FEE AMOUNTS.—

(1) TOTAL FEE REVENUES FOR APPLICATION AND SUPPLEMENT FEES.—Section 740(b)(1) (21 U.S.C. 379j–12(b)(1)) is amended—

(A) by striking ''and supplemental animal drug application fees'' and inserting ''and supplemental and other animal drug application fees''; and

(B) by striking ''$1,250,000'' and all that follows through the period at the end and inserting ''$3,815,000 in fiscal year 2009, $4,320,000 in fiscal year 2010, $4,862,000 in fiscal year 2011, $5,442,000 in fiscal year 2012, and $6,061,000 in fiscal year 2013.''.

(2) TOTAL FEE REVENUES FOR PRODUCT FEES.—Section 740(b)(2) (21 U.S.C. 379j–12(b)(2)) is amended by striking ''$1,250,000'' and all that follows through the period at the end and inserting ''$3,815,000 for fiscal year 2009, $4,320,000 for fiscal year 2010, $4,862,000 for fiscal year 2011, $5,442,000 for fiscal year 2012, and $6,061,000 for fiscal year 2013.''.

(3) TOTAL FEE REVENUES FOR ESTABLISHMENT FEES.—Section 740(b)(3) (21 U.S.C. 379j–12(b)(3)) is amended by striking ''$1,250,000'' and all that follows through the period at the end and

inserting ''$3,815,000 for fiscal year 2009, $4,320,000 for fiscal year 2010, $4,862,000 for fiscal year 2011, $5,442,000 for fiscal year 2012, and $6,061,000 for fiscal year 2013.''.

(4) TOTAL FEE REVENUES FOR SPONSOR FEES.—Section 740(b)(4) (21 U.S.C. 379j–12(b)(4)) is amended by striking ''$1,250,000'' and all that follows through the period at the end and inserting ''$3,815,000 for fiscal year 2009, $4,320,000 for fiscal year 2010, $4,862,000 for fiscal year 2011, $5,442,000 for fiscal year 2012, and $6,061,000 for fiscal year 2013.''.

(c) ADJUSTMENTS TO FEES.—Section 740(c) (21 U.S.C. 379j–12(c)) is amended—

(1) by striking paragraph (1);

(2) by redesignating paragraphs (2) through (5) as paragraphs (1) through (4), respectively;

(3) in paragraph (1), as so redesignated—

(A) in the matter preceding subparagraph (A), by striking ''After the fee revenues are adjusted for inflation in accordance with paragraph (1), the fee revenues shall be further adjusted each fiscal year after fiscal year 2004'' and inserting ''The fee revenues shall be ad-

justed each fiscal year after fiscal year 2009''; and

(B) in subparagraph (B), by striking '', as adjusted for inflation under paragraph (1)''; and

(4) in paragraph (2), as so redesignated—

(A) by striking ''2008'' each place it appears and inserting ''2013''; and

(B) by striking ''2009'' and inserting ''2014''.

(d) AUTHORIZATION OF APPROPRIATIONS.—Subparagraphs (A) through (E) of section 740(g)(3) (21 U.S.C. 379j–12(g)(3)) are amended to read as follows:

''(A) $15,260,000 for fiscal year 2009;

''(B) $17,280,000 for fiscal year 2010;

''(C) $19,448,000 for fiscal year 2011;

''(D) $21,768,000 for fiscal year 2012; and

''(E) $24,244,000 for fiscal year 2013;''.

(e) OFFSET.—Section 740(g)(4) (21 U.S.C. 379j–12(g)(4)) is amended to read as follows:

''(4) OFFSET.—If the sum of the cumulative amount of fees collected under this section for fiscal years 2009 through 2011 and the amount of fees estimated to be collected under this section for fiscal

year 2012 exceeds the cumulative amount appropriated under paragraph (3) for the fiscal years 2009 through 2012, the excess amount shall be credited to the appropriation account of the Food and Drug Administration as provided in paragraph (1), and shall be subtracted from the amount of fees that would otherwise be authorized to be collected under this section pursuant to appropriation Acts for fiscal year 2013.''.

SEC. 4. REAUTHORIZATION; REPORTING REQUIREMENTS.

Part 4 of subchapter C of chapter VII (21 U.S.C. 379j–11 et seq.) is amended by inserting after section 740 the following:

''SEC. 740A. REAUTHORIZATION; REPORTING REQUIREMENTS.

''(a) PERFORMANCE REPORT.—Beginning with fiscal year 2009, not later than 60 days after the end of each fiscal year during which fees are collected under this part, the Secretary shall prepare and submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate a report concerning the progress of the Food and Drug Administration in achieving the goals identified in the letters described in section 1(c) of the Animal Drug User Fee Amendments of 2008 toward

expediting the animal drug development process and the review of the new and supplemental animal drug applications and investigational animal drug submissions during such fiscal year, the future plans of the Food and Drug Administration for meeting the goals, the review times for abbreviated new animal drug applications, and the administrative procedures adopted by the Food and Drug Administration to ensure that review times for abbreviated new animal drug applications are not increased from their current level due to activities under the user fee program.

''(b) FISCAL REPORT.—Beginning with fiscal year 2009, not later than 120 days after the end of each fiscal year during which fees are collected under this part, the Secretary shall prepare and submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate a report on the implementation of the authority for such fees during such fiscal year and the use, by the Food and Drug Administration, of the fees collected during such fiscal year for which the report is made.

''(c) PUBLIC AVAILABILITY.—The Secretary shall make the reports required under subsections (a) and (b) available to the public on the Internet Web site of the Food and Drug Administration.

''(d) REAUTHORIZATION.—

''(1) CONSULTATION.—In developing recommendations to present to the Congress with respect to the goals, and plans for meeting the goals, for the process for the review of animal drug applications for the first 5 fiscal years after fiscal year 2013, and for the reauthorization of this part for such fiscal years, the Secretary shall consult with—

''(A) the Committee on Energy and Commerce of the House of Representatives;

''(B) the Committee on Health, Education, Labor, and Pensions of the Senate;

''(C) scientific and academic experts;

''(D) veterinary professionals;

''(E) representatives of patient and consumer advocacy groups; and

''(F) the regulated industry.

''(2) PRIOR PUBLIC INPUT.—Prior to beginning negotiations with the regulated industry on the reauthorization of this part, the Secretary shall—

''(A) publish a notice in the Federal Register requesting public input on the reauthorization;

''(B) hold a public meeting at which the public may present its views on the reauthoriza-

tion, including specific suggestions for changes to the goals referred to in subsection (a);

"(C) provide a period of 30 days after the public meeting to obtain written comments from the public suggesting changes to this part; and

"(D) publish the comments on the Food and Drug Administration's Internet Web site.

"(3) PERIODIC CONSULTATION.—Not less frequently than once every month during negotiations with the regulated industry, the Secretary shall hold discussions with representatives of patient and consumer advocacy groups to continue discussions of their views on the reauthorization and their suggestions for changes to this part as expressed under paragraph (2).

"(4) PUBLIC REVIEW OF RECOMMENDATIONS.—After negotiations with the regulated industry, the Secretary shall—

"(A) present the recommendations developed under paragraph (1) to the Congressional committees specified in such paragraph;

"(B) publish such recommendations in the Federal Register;

"(C) provide for a period of 30 days for the public to provide written comments on such recommendations;

"(D) hold a meeting at which the public may present its views on such recommendations; and

"(E) after consideration of such public views and comments, revise such recommendations as necessary.

"(5) TRANSMITTAL OF RECOMMENDATIONS.—Not later than January 15, 2013, the Secretary shall transmit to the Congress the revised recommendations under paragraph (4), a summary of the views and comments received under such paragraph, and any changes made to the recommendations in response to such views and comments.

"(6) MINUTES OF NEGOTIATION MEETINGS.—

"(A) PUBLIC AVAILABILITY.—Before presenting the recommendations developed under paragraphs (1) through (5) to the Congress, the Secretary shall make publicly available, on the Internet Web site of the Food and Drug Administration, minutes of all negotiation meetings conducted under this subsection between

the Food and Drug Administration and the regulated industry.

''(B) CONTENT.—The minutes described under subparagraph (A) shall summarize any substantive proposal made by any party to the negotiations as well as significant controversies or differences of opinion during the negotiations and their resolution.''.

SEC. 5. PERIODIC DRUG EXPERIENCE REPORTS.

(a) REPORTING PERIOD; SUBMISSION DATE.—With respect to periodic drug experience reports on antibiotic new animal drugs that are required under section 514.80(b)(4) of title 21, Code of Federal Regulations, the Secretary of Health and Human Services (in this section referred to as the ''Secretary'') shall modify such section to provide that, in the case of each such report that is required on an annual basis—

(1) the reporting period is the calendar year, beginning with calendar year 2008; and

(2) the report on such a period is due not later than March 31 following the end of the period.

(b) TRANSITIONAL PROVISION.—

(1) IN GENERAL.—With respect to periodic drug experience reports under section 514.80(b)(4) of title 21, Code of Federal Regulations, that, but

for the enactment of this Act, would be due during the transitional period, the Secretary shall ensure that implementation of this section does not result in—

(A) excluding any portion of calendar year 2007 from consideration; or

(B) delaying the submission date so that a gap of more than 12 months occurs between the submission of such reports.

(2) DEFINITION.—In this subsection, the term ''transitional period'' means the period beginning on the effective date of the final regulation published pursuant to subsection (c) and ending on March 30, 2009.

(c) RULEMAKING PROCEDURE.—To carry out this section, the Secretary shall publish a final regulation not later than 60 days after the date of the enactment of this Act. For purposes of such rulemaking, good cause (as such term is used in section 553(b) of title 5, United States Code) shall be considered to exist.

SEC. 6. SAVINGS CLAUSE.

Notwithstanding section 5 of the Animal Drug User Fee Act of 2003 (21 U.S.C. 379j–11 note), and notwithstanding the amendments made by this Act, part 4 of subchapter C of chapter VII of the Federal Food, Drug, and

Cosmetic Act (21 U.S.C. 379j–11 et seq.), as in effect on the day before the date of the enactment of this Act, shall continue to be in effect with respect to animal drug applications and supplemental animal drug applications (as defined in such part as of such day) that on or after September 1, 2003, but before October 1, 2008, were accepted by the Food and Drug Administration for filing with respect to assessing and collecting any fee required by such part for a fiscal year prior to fiscal year 2009.

SEC. 7. EFFECTIVE DATE.

The amendments made by sections 2, 3, and 4 shall take effect on October 1, 2008, or the date of the enactment of this Act, whichever is later, except that fees under part 4 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act, as amended by this Act, shall be assessed for all animal drug applications and supplemental animal drug applications received on or after October 1, 2008, regardless of the date of the enactment of this Act.

SEC. 8. SUNSET DATES.

(a) AUTHORIZATION.—The amendments made by sections 2 and 3 cease to be effective October 1, 2013.

(b) REPORTING REQUIREMENTS.—The amendment made by section 4 ceases to be effective January 31, 2014.

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